

CONSENT TO TAKE PART IN A RESEARCH STUDY (Hawaii)

Title of study: An Investigation of the Epidemiology of Hearing Loss in Infants and Young Children

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Sponsor: Hawaii Department of Health
Centers for Disease Control and Prevention

INTRODUCTION:

We invite you and your child to be in a research study about the causes of hearing loss in infants and young children. You are asked to be in this study because your child has a hearing loss. It is voluntary for you to be in this study, and you may stop at any time without penalty or loss of benefits. It may not help you to be in this research study. However, we may learn things that will help others, and we may learn the cause of your child's hearing loss.

PURPOSE OF THE STUDY:

The purpose of this study is to learn more about causes of hearing loss in young children. A part of this study is to find out how much hearing loss is due to genes. The Hawaii Department of Health and the Centers for Disease Control and Prevention (CDC) are working together on this study to look into the causes of hearing loss. The study will have about 64 children from Hawaii.

BACKGROUND:

About 1 in 300 infants are born with hearing loss. Changes in genes cause this hearing loss for about half of the children. Some children have hearing loss caused by infections, while other children have no known cause. Based on research done mostly with older children, some scientists believe that a gene called connexin 26 causes about 20% percent of all hearing loss in newborns. This needs to be studied more in young children, including those children identified by the Newborn Hearing Screening Program. This study will offer genetic testing for the connexin 26 gene and two mitochondrial genes. These tests are currently available clinically and are not experimental. About 64 children in Hawaii will take part in the study.

STUDY PROCEDURES

If you agree that you and your child will take part in this study:

1. You will be asked for permission for this study to obtain medical records.
2. An appointment will be made with a genetic counselor. You will be asked questions about your child's medical and family history. Genetic testing will be explained. This may take up to 2 hours.

3. An appointment will be made with a genetic counselor and a genetics doctor (geneticist). The doctor will do a physical examination of your child. A picture of your child's face will be taken. This photo may help the doctor figure out the cause of your child's hearing loss, and is a standard part of a genetics evaluation. The photo will be kept in your child's study chart within a locked file cabinet. The photo will be destroyed when all of the data for the study has been analyzed. The appointment may take up to 2 hours.
4. If you choose, a genetic test will be done by taking blood or a cheek swab from your child. To get a blood sample, a person with special training will use a clean needle to take about 2 teaspoons (10 milliliters) and put it into a glass tube. The amount of blood is depending on your child's age, height and weight. To get a cheek swab, a toothbrush will be used to swab the inside of your child's cheek. This method is simple and painless, but there may not be enough sample for genetic testing and we may need to ask for a blood sample.
5. If the test shows that your child has changes in the genes which cause hearing loss, the genetic counselor will contact you by telephone to tell you the results. An appointment will be made to explain the test results and answer questions. Results will be sent to your child's doctor if you sign a written consent form.

OR

If a change in your child's genes is *not* found, the genetic counselor will call you to tell you the results. It may only mean that we have not yet found any gene that causes the hearing loss in your child. Not all causes of hearing loss are currently known. Results will be sent to your child's doctor if you sign a written consent form.

Your child may be in the study from 2 to 9 months, depending on how soon appointments can be made for you and your child to see the genetics doctor.

RISKS

Although they are small, there are some risks to doing the genetic testing in this study.

We could find that relationships among family members are different than reported to us. If this is found, we will not report this information back to you.

The risks for giving a blood sample are minimal and may include mild pain or a bruise at the place where the blood is taken. Sometimes a person may faint or feel faint when blood is taken. The risk of infection is slight since only sterile one-time equipment will be used

There are no medical risks for taking the cheek swab other than the discomfort that some children feel with the brush against the cheek. This sometimes could be fearful for an infant.

Different people react to results from genetic testing in different ways. Some people find it comforting to find a reason for their child's condition, while others find it difficult emotionally. In cases where no cause is found, some people find this frustrating and disappointing.

We do not expect risks to your child beyond those we have already told you about. However, there may be risks that we cannot predict. We will inform you if there are any new risks.

BENEFITS

We hope that this study will help us to better understand the cause of your child's hearing loss. This may or may not help you or your child. If we find things of medical significance to you during this study, we will inform you. This study will help us learn more about the causes of hearing loss. It may also help to improve follow-up for the Newborn Hearing Screening Program, and this may help other young children with hearing loss.

COSTS

There will be no cost to you to take part in this study. You will not be asked to pay for any of the things done as part of this study.

The cost of any follow-up care is not part of the study. You will be responsible for this cost. If your child needs a referral to another specialist such as an ear nose and throat doctors, this would be done through your regular doctor and be under your own insurance.

COMPENSATION

There will be no compensation (payment) to you to participate in this research study.

CONFIDENTIALITY

All information concerning you and your child will be kept confidential (private) to the extent allowed by law. Records with your child's name and photograph will be kept in locked files, and only study staff will be allowed to look at them. Your child's picture will be destroyed once data analysis for the study has been completed. Your name, your child's picture, or other facts that might point to you will not appear when the study results are presented or published. No names or photographs will ever be published in reports. Health and life insurance companies can insist that you give permission for the release of records from this study before they approve a policy. If we learn something that would endanger you, your child, or others, we may discuss it with you. The University of Hawaii Committee on Human Studies also has the right to review research records.

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. If you decide not to be in the study, you will not be penalized or lose any benefits to which you are otherwise entitled, and you will not lose any health care services that you expect to get apart from this study. You can stop being in this study at any time for any reason, and you will not be penalized or lose any benefits to which you are otherwise entitled.

ALTERNATIVES

If you do not want your child to be in this study, but you want your child to see a geneticist or have the genetic testing, you will need to arrange this through your child's health care provider. You will be responsible for the cost of this.

NEW FINDINGS

Any important new finding discovered during this study that may make a difference in your willingness for your child to continue in the research study will be given to you.

RIGHT OF INVESTIGATOR TO WITHDRAW SUBJECTS

The project staff may withdraw you from the study, and in the event of this happening, we will explain the reasons to you.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY

Although it is not likely, if your child is hurt or injured as a result of this study, the study will pay reasonable costs for emergency and temporary medical treatment for your child which is not covered by your insurance.

PARTIES TO CONTACT

Contact the Principal Investigator (listed on the first page of this form) if you have any questions about the research study, or in the event that injury occurs as a result of this study.

An Institutional Review Board is a group of people who review all studies done at places such as health departments, hospitals, and universities, to make sure that the rights of people in studies are protected. Contact the following Institutional Review Boards if you cannot obtain satisfactory answers to your questions, or have questions about your rights while you are in the study:

Hawaii Department of Health
Human Research Assistance and Evaluation Committee
Betty Wood, Executive Secretary
P.O. Box 3378
Honolulu, HI 96801-3378
Phone: (808) 586-4530

Committee on Human Studies
University of Hawaii
2540 Maile Way
Honolulu, HI 96822
Phone: (808) 956-5007

CONSENT

I certify that I have read and understand the information described above. My questions about study procedures and other matters have been answered. I have been advised that I can withdraw my consent and stop being in the study at any time without prejudice.

I give my permission for my child to take part in this research study. I understand that this consent does not waive any of my legal rights. I understand that it does not release the principle investigator or the institution or any employee or agent thereof for liability for negligence.

Child's Name (Print)

Birth Date

Parent or Legal Guardian Name (Print)

Parent or Legal Guardian Signature

Date

CONSENT TO SAVE SAMPLES

You can decide whether we (the laboratory doing the testing for this study) can keep a sample of your child's blood or cheek swab for future research. If you decide we can keep it, the sample will be stored in a safe and secure place for an indefinite amount of time. The choice you make will not affect your child's care. If you decide now that we can store your child's sample, you may change your mind at any time. In that case, contact us and tell us that you do not want us to keep your child's sample any longer, and the sample will be destroyed.

If you decide that we can store your child's sample, it would only be used to study how genes relate to hearing loss. It would not be used to test genes related to other conditions, or for any additional research.

Please read the choices below and select the option you prefer:

- I do not want my child's sample saved.
- I want my child's sample saved for future research. I want this sample to have a number which connects the sample to me and my child. I must be asked for permission each time someone wants to use it for future research.
- I want my child's sample saved for future research. I want this sample to have a number which connects the sample to me and my child. I do not need to be contacted when someone wants to use it for future research.
- I want my child's sample be saved for future research, but with no number that connects the sample to me or my child. *(Please note: For this choice, we will not be able to contact you if anything of medical significance is found in the future.)*

My signature below is in support of my choice that I have indicated above.

Parent or Legal Guardian Signature

Date